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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,431	07/30/2002	David M. Hockenberry	14538A-004610US	3708

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EXAMINER

OWENS, AMELIA A

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,431

Applicant(s)

HOCKENBERRY ET AL.

Examiner

Amelia A. Owens

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/905 AND 11/30/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13, 15, 17-19, 21, 22 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-13, 21, 22 and 24-26 is/are allowed.
- 6) ☒ Claim(s) 15, 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-10,14,16,20,23 have been canceled. Claims 11-13,15,17-19,21,22,24-26 are pending.

Claim Rejections - 35 USC § 112

2. The rejection of claims 1-13,15,20-21,23 under 35 USC 112, 2nd paragraph has been dropped as the claims have been canceled and/or amended.

3. The rejection of claims 1,5,6,9-11,13, 14,17,20 under 35 USC 112, 1st paragraph has been dropped as the claims have been canceled and/or applicants comments are persuasive.

4. Claims 15,17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). All of the factors have been considered but only the most relevant will be discussed below.

The nature of the invention: The nature of the invention is the method of identifying a composition that induces apoptosis. See claims.

The state of the prior art and predictability: The state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). The high degree of unpredictability is recognized in the apoptosis art. A slight change in the structure of the compound would drastically change its biological activity in vitro. In the in vivo system, the degree of unpredictability multiplies in view of the complexity of the physiological conditions.

Art Unit: 1625

Guidance and working examples: It is not seen where the claimed assay is used to identify a single 'candidate compound' that induces apoptosis. The term is employed with no indication given as to what they really are. One should be able, from reading of the claims, determine what that claim does or does not encompass. Why? Because that claim preclude others from making, using, or selling that compound for 20 years. Therefore, one must know what compound is being claimed.

In the pharmaceutical area, declarations under 37 CFR 1.132 are often employed to set forth the advantage of a particular substituent. The definition and claiming of substituents is extremely important in the claims of the application. Applicant should not be able to preempt future work of others by means of claims to compounds they themselves did not make and test.

The unknown 'candidate compound' is not believed to meet the requirements of 35 USC 112, first paragraph. One must first conceive of the 'candidate compound'. Then one must, by preparing the compound himself, determine if the compound(s) work. How can applicants regard as their invention inexact concepts? The breadth of which they could not have possibly check out with representative exemplification. The terms are not finite.

Since insufficient guidance and teaching have been provided by the specification, the skilled artisan, even with high level of skill, is unable to use the instant assay as claimed without undue experimentation.

5. Claims 15,17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed method encompasses unidentified compounds, and as yet unidentified compounds a description of which is not found in the specification. There is no description of the 'candidate compound' in the specification.

Thus, the written description is considered inadequate here in the specification. Conception of the intended 'candidate compound' should not be the role of the reader. Applicant should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely and invitation to experiment. If

Art Unit: 1625

you (the public) find that it works, I claim it, is not a proper basis of patentability. In re Kirk, 153 USPQ 48 at page 53.

Certain Observations

6. Apoptosis is programmed cell death. Cancer therapy agents are known to induce apoptosis in tumor cells. See specification at page 3 lines 9-10.
7. Members of the Bcl-2 family are known regulators of apoptotic cell death and survival. See specification page 1 lines 23-27.
8. Apoptosis-associated diseases are defined in the specification at page 13 lines 13-25.
9. Modes of administration - intravenous, subcutaneous, intramuscular, intradermal, transdermal, intrathecal, intracerebral, intraperitoneal, epidural, oral – are well within the purview of the skilled artisan in the pharmaceutical arts.
10. Antimycin A is known to inhibit activity of Bcl-2 family member proteins. See Tzung, Antimycin A mimics a cell-death-inducing Bcl-2 homology domain 3, Nature Cell Biology, Vol.3, (2001) 183-191.
11. The prior art neither teaches nor suggests the claimed compositions and method. In the absence of any evidence or apparent reason why the claimed compounds do not possess the disclosed utility, the allegation of utility in the specification must be accepted as correct. In re Kamal et al, 158 USPQ 320; Ex parte Krenzer, 199 USPQ 227.

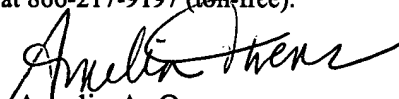
The claimed compounds are antimycin derivatives. Compounds similar in structure are expected to have similar properties. Thus, the claimed compositions containing antimycin derivatives would be expected to inhibit activity of Bcl-2 family member proteins.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1625

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Amelia A. Owens".

Amelia A. Owens

Primary Examiner

Art Unit 1625